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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,176

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Daisuke Matsumoto

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

WOO, JULIAN W

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,176	<b>Applicant(s)</b> MATSUMOTO, DAISUKE	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-22 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/28/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 18 is objected to because of an informality in line 2, which can be corrected as follows: "potion" should be replaced by --portion--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 14, "the cap" and "the first and second engagement means" lack antecedent bases.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7-14, 16, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Duchon et al. (5,879,311). Duchon discloses, at least in the figures and in col. 6, line 15 to col. 8, line 60; col. 9, lines 26-45; and col. 10, lines 9-30; a lancing

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unit or lancing apparatus including a lancing member (150, see fig. 11) with an engagement surface oriented toward a rear side of a housing, a housing (12), and a support member (102 and 100 combined), where the lancing member is capable of being fitted and mounted to a movable member (130), where the support member includes an engagement means (100, see fig. 6); where the lancing member includes a needle (154) and a body (152), where the body has an outer circumferential surface formed with a projection (156, 158) or stepped portion (surrounding 156 or 158), where the engagement means (100) includes at least one projection (113) extending in direction of the needle and formed with a pawl, where the engagement means includes a plurality of projections (108) that can clip the lancing member (to element 12), where the stepped portion of the body comprises a flange (adjacent to element 158--see fig. 11), where the support member includes a tubular portion 9102), where the lancing unit includes an analytical part (164) and additional engagement means (162) each with an additional engagement projection, where the analytical part is removably supported by the support member, where the analytical part has an engagement surface oriented toward a rear side of the housing, where the engagement means and the additional engagement means are arranged to enter the housing together, where the support member includes a partition wall (115), where a cap (S), the lancing member, and the analytical part are arranged in a first chamber and the engagement means and additional engagement means are arranged in a second chamber, where the lancing apparatus includes a biasing means (90), a latching means (84), a latch releasing means (46, and a stopper (88, see col. 9, lines 26-39); where the stopper is capable of

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being positioned in a movement path of the movable member (130), where the housing is provided with a holding portion (near the front opening or near the rear) for removably holding an analytical part (164 or 52), where the support member includes a cap (102) for covering the needle (at least the sides of the needle) and removably supporting the lancing member, and where the lancing unit includes a boundary portion (spring 132) between the body and the cap (102), the spring being more liable to receive stress than other portions of the body and the cap.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon et al. (5,879,311) in view of Mitchen (5,014,718). Duchon et al. disclose the invention substantially as claimed, but do not disclose a lid for hermetically closing the first

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chamber. Mitchen teaches, at least in figures 1 and 2 and col. 2, lines 31-54; a lancing unit with a lid (11) for closing a first chamber (at 15 and 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Mitchen, to modify the lancing unit of Duchon et al., so that it includes a lid. Such a lid would protect at least the internal parts of the lancing unit from contaminants prior to use of the lancing unit.

8. Claims 17-19 are rejected under 35 U.S.C. 102(b) as anticipated by Duchon et al. (5,879,311) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Duchon et al. (5,879,311) in view of Schraga (6,454,828). Under 35 U.S.C. 102(b), Duchon et al. disclose, at least in figures 2, 3A, 5, and 12, a lancing member removing tool including a removal tool (16 and 22 combined, see fig. 3A) comprising an engagement means (130) for entering the housing through a front-end opening with an engagement surface of the lancing member (150), where the removal tool includes a support member with a tubular portion (102), and an additional engagement means (22) provided at (i.e., engaged with) the support member, wherein when the tubular portion is slid along and fitted to the front end of the housing with an analytical part (24), the additional engagement means enters the housing and engages an engagement surface of the analytical part. Alternatively and arguably and under 35 U.S.C. 103(a): Duchon et al. disclose a lancing apparatus with a removable lancing member (150), but do not disclose a removal tool with engagement means for entering the housing for engagement with an engagement surface of the lancing member, where the engagement surface is oriented toward a rear side of the housing, where the tool includes a support member including a tubular

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portion and an additional engagement means, the additional engagement means being capable of entering the opening of the housing and engaging an engagement surface of an analytical part (154, which causes blood to be released for analysis). Schraga teaches, at least in figures 6-9 and in col. 4, lines 11-46; a removal tool (24) including an engagement means (32) for engaging an engagement surface (34) of a lancing member and an additional engagement means (28) for engaging an engagement surface of an analytical part (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Scharga, to include a removal tool with the lancing apparatus of Duchon et al. Such a tool would allow the needle to be safely covered after its use and allow the lancing member to be grasped (via the tool) and removed from the housing.

***Allowable Subject Matter***

9. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a lancing unit including, inter alia, a lancing member and a support member with a plurality of engagement projections, where the lancing member includes a needle and a body with a stepped portion, the stepped portion including a flange, wherein, when the engagement projections are inserted into a housing, each of the engagement

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projections resiliently deforms due to contact with the stepped portion, so that pawls of the engagement projections pass over the stepped portion.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).



***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773